

510(k) Summary

EchoTech 3D Imaging Systems

APR 04 2002

Easy3D Family
3D FreeScan
EasyArchive
Quanticon
EasyStress

Submitter (Consultant) Name and Address

Morningstar Consulting Group, Inc.
P. O. Box 219
Indian Hills, CO 80454

Submitter (Consultant) Contact Person

Kevin Morningstar, Senior Consultant
phone: (303) 697-8198
fax: (303) 697-7907

Sponsor Name and Address

EchoTech 3D Imaging Systems Inc
555 Burbank St. Unit A
Broomfield, CO 80020

Sponsor Contact Person

Mr. Anthony Harris
Manager of Operations
phone 303-438-8455
fax 303-438-8530

Manufacturer Name and Address

EchoTech 3D Imaging Systems GmbH
Zeppelinstr. 4
D-85399 Hallbergmoos
Germany

Manufacturer Contact Person

Peter Wlczek, Product Line Manager
phone: 011 49 811 5556 0
fax: 011 49 811 5556 20

Common, Classification & Proprietary Names

Common Name:	Digital ultrasound image analysis system
Classification Name:	Picture Archiving and Communications System (PACS)
Proprietary Name:	Easy3D, 3D FreeScan, EasyArchive, Quanticon, and EasyStress

Classification

Class: II
Panel: Radiology
CFR Section: 21 CFR 892.2050
Product Code: LLZ (image processing system)

Predicate Devices

EchoTech 3D FreeScan	K980308	May 6, 1998
Tom-Tec Echo-Scan	K963807	December 18, 1996

Device Description

The following products produced by Echotech 3D Imaging Systems are included in this 510(k) premarket notification:

- Easy3D Family
- 3D FreeScan
- EasyArchive
- Quanticon
- EasyStress

All of the subject products are accessories to diagnostic ultrasound imaging systems. The products are high performance computer systems based on Intel motherboard and WindowsNT standards. The systems incorporate commercially available image digitizer circuit boards for acquisition, storage, annotation, reporting, and retrieval of ultrasound image data. They also incorporate proprietary image processing software developed by EchoTech 3D Imaging Systems.

The EchoTech Easy3D Family system is a high performance computer system based on Intel motherboard and WindowsNT standards. It incorporates a commercially available image digitizer circuit board for acquisition, storage and retrieval of ultrasound image data. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The system acquires either heart cycle (R-Peak) triggered or nontriggered sequences of 2D ultrasound images (B/W and Color). The 2D ultrasound images are acquired through video output port of the host ultrasound system as the ultrasound transducer is moved across the patient scan site. The resulting set of digitized 2D images is then converted into a 3D data volume under the assumption that a predefined scan movement was followed. In this step redundant gray values are eliminated, gaps are filled by a trilinear interpolation and the images are sorted depending on the time delay to the R-Peak. The acquisition process might be R-Peak triggered by the heart cycle. This is done by importing an Audio or TTL signal from the Physio module of the ultrasound system.

The EchoTech 3D FreeScan system is a high performance computer system based on Intel motherboard and WindowsNT standards. It incorporates a commercially available image digitizer circuit board for the acquisition, storage and retrieval of digital dynamic 3D ultrasound image data sets. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The device records ultrasound transducer spatial position in six degrees of freedom during use. Coordinate tracking is achieved with a miniature magnetic field sensor within a transmitted pulsed magnetic field. This is done by attaching a plastic holding plate to the probe of the host ultrasound system, to which the receiver of an electromagnetic sensor device is attached.

2D ultrasound images are acquired triggered sequentially in a series of steps as the ultrasound transducer is moved across the patient scan site. The resulting set of digitized 2D images is then converted into a 3D data volume. The acquisition process is R-Peak triggered by the heart cycle. This is done by importing an Audio or TTL signal from the Physio module of the ultrasound system.

The commercially available coordinate sensor device consists of an IBM compatible PC board, a transmitter and a receiver. The transmitter generates a spherical magnetic field and the receiver can be moved anywhere within 1m of the transmitter to generate a set of 3 translational and 3 angulation values.

The 3D FreeScan system digitizes R-Peak triggered the ultrasound images from the video output port of the host ultrasound system through a video cable. The images are stored in the computer memory. In a postprocessing step the oblique images are transformed into a Cartesian coordinate system. In this step redundant gray values are eliminated, gaps are filled by a trilinear interpolation and the images are sorted depending on the time delay to the R-Peak.

The EchoTech EasyArchive system is a high performance computer system based on Intel motherboard and WindowsNT standards. It incorporates a commercially available image digitizer circuit board for acquisition, storage and retrieval of ultrasound image data. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The system acquires single 2D ultrasound images or sequences of 2D ultrasound images. The EasyArchive system digitizes the ultrasound images from the video output port of the host ultrasound system through a video cable. The images or sequences are stored in the computer memory. The data can be stored along with patient administrative data in a data base on the EasyArchive harddisk or on removable media for later display and retrieval.

The EchoTech QuantiCon system is a high performance computer system based on Intel motherboard and WindowsNT standards. It incorporates a commercially available image digitizer circuit board for acquisition, storage and retrieval of ultrasound image data. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The system acquires either heart cycle (R-Peak) triggered or nontriggered sequences of 2D ultrasound images. In the sequence of images multiple Regions Of Interest (ROI) can be selected. Inside these regions the average gray value or the number of color pixel is calculated over time.

The QuantiCon system digitizes the ultrasound images from the video output port of the host ultrasound system through a video cable. The trigger signal for the acquisition process is taken from the ultrasound system either as an Audio beep or as a TTL signal. The images are stored in the computer memory. In a postprocessing step the

images are lossless compressed (runlength compression). The postprocessed data can be stored along with patient administrative data in a data base on the QuantiCon harddisk or on removeable media for later display and retrieval.

The EchoTech EasyStress system is a high performance computer system based on Intel motherboard and WindowsNT standards. It incorporates a commercially available image digitizer circuit board for acquisition, storage and retrieval of ultrasound image data. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The system acquires heart cycle (R-Peak) triggered sequences of 2D ultrasound images. Corresponding to the guidelines of the American Society of Echocardiographie ASE 16 sequences can be acquired. (4 stress phases and for each stress phase four standard views of the heart). The sequences can be synchronized replayed either sorted after stress phase or standard views. In the replay mode wall motion scoring WMS can be carried out following the guidelines of the ASE. The EasyStress system digitizes the ultrasound images from the video output port of the host ultrasound system through a video cable. The trigger signal for the acquisition process is taken from the ultrasound system either as an Audio beep or as a TTL signal. The images are stored in the computer memory. In a postprocessing step the images are lossless compressed (runlength compression). The postprocessed data can be stored along with patient administrative data in a data base on the EasyStress harddisk or on removeable media for later display and retrieval.

Intended Use

The EchoTech Easy3D system is indicated for acquisition of related sets of 2D ultrasound images and 3D reconstruction of ultrasound images. It is intended to acquire, analyze, store, and retrieve digital ultrasound images for computerized 3D image processing. Easy3D is an add-on accessory to existing diagnostic ultrasound systems. Easy3D employs freehand scanning without the use of a coordinate and position sensor, therefore, the extension of the data set in the scanning direction is unknown. The images are not intended for use in diagnosis or quantitative measurements. The Easy3D is intended as a general purpose digital 3D ultrasound image processing tool for use in obstetrics for qualitative evaluation of deformities and determination of the need for further fetal ultrasound studies.

The EchoTech 3D FreeScan system is indicated for acquisition of related sets of 2D ultrasound images and 3D reconstruction of ultrasound images. It is intended to acquire, analyze, store, and retrieve digital ultrasound images for computerized 3D image processing. Easy3D is an add-on accessory to existing diagnostic ultrasound systems. Easy3D employs freehand scanning with the use of a coordinate and position sensor and, optionally, with heart cycle (R-Peak) triggering, which enables cardiovascular imaging.

The EchoTech EasyArchive system is indicated to acquire, digitize, archive, and retrieve single or sequences of 2D ultrasound images. EasyArchive is an add-on accessory to existing diagnostic ultrasound systems. EasyArchive is intended as a general purpose digital ultrasound image processing and archiving tool for use in

radiology, neurology, gastroenterology, urology, surgery, orthopedics, cardiology, oncology, obstetrics and gynecology.

The EchoTech Quanticon system is indicated in the acquisition of either heart cycle (R-Peak) triggered or nontriggered sequences of 2D ultrasound images for use in the evaluation of contrast agent-based ultrasound exams. In the sequence of images multiple Regions Of Interest (ROI) can be selected. Inside these chosen regions the average gray value or the number of color pixels is calculated over time. Quanticon is intended as an add-on accessory to existing diagnostic ultrasound systems. Quanticon is intended as a general digital ultrasound processing and archiving tool for use in cardiology, radiology, and neurology.

The EchoTech EasyStress system is indicated for the acquisition of heart cycle (R-Peak) triggered sequences of 2D ultrasound images for use in performing, scoring, measuring, reporting, and archiving stress echo studies. The EasyStress system utilizes the ASE Standard for Wall Motion Scoring to quantify wall motion abnormalities of the heart. EasyStress is an add-on accessory to existing diagnostic ultrasound systems. EasyStress is a digital ultrasound image processing and archiving tool for use in cardiology.

Verification and Validation Procedures

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Additional system testing was done by a third party standards test house.

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally and by third parties conforms to the system performance specifications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 04 2002

EchoTech 3D Imaging Systems, Inc.
% Mr. Kevin Morningstar
President & Senior Consultant
Morningstar Consulting Group, Inc.
P.O. Box 219
INDIAN HILLS CO 80454

Re: K013088

Trade/Device Name: EchoTech Easy 3D, 3D FreeScan,
EasyArchive, Quanticon, EasyStress

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Number: 21 CFR 892.2050

Regulatory Name: Picture archiving and
communications system

Regulatory Class: II

Product Code: 90 IYO and LLZ

Dated: March 4, 2002

Received: March 6, 2002

Dear Mr. Morningstar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

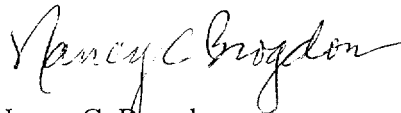
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013088

Device Name EchoTech Easy3D System

Indications for Use:

The EchoTech Easy3D is indicated for acquisition of related sets of 2D ultrasound images and 3D reconstruction of ultrasound images. It is intended to acquire, analyze, store, and retrieve digital ultrasound images for computerized 3D image processing. Easy3D is an add-on accessory to existing diagnostic ultrasound systems. Easy3D employs freehand scanning without the use of a coordinate and position sensor, therefore, the extension of the data set in the scanning direction is unknown. The images are not intended for use in diagnosis or quantitative measurements. The Easy3D is intended as a general purpose digital 3D ultrasound image processing tool for use in obstetrics for qualitative evaluation of deformities and determination of the need for further fetal ultrasound studies.

The EchoTech 3D FreeScan system is indicated for acquisition of related sets of 2D ultrasound images and 3D reconstruction of ultrasound images. It is intended to acquire, analyze, store, and retrieve digital ultrasound images for computerized 3D image processing. Easy3D is an add-on accessory to existing diagnostic ultrasound systems. Easy3D employs freehand scanning with the use of a coordinate and position sensor and, optionally, with heart cycle (R-Peak) triggering, which enables cardiovascular imaging.

The EchoTech EasyArchive system is indicated to acquire, digitize, archive, and retrieve single or sequences of 2D ultrasound images. EasyArchive is an add-on accessory to existing diagnostic ultrasound systems. EasyArchive is intended as a general purpose digital ultrasound image processing and archiving tool for use in radiology, neurology, gastroenterology, urology, surgery, orthopedics, cardiology, oncology, obstetrics and gynecology.

The EchoTech Quanticon system is indicated in the acquisition of either heart cycle (R-Peak) triggered or nontriggered sequences of 2D ultrasound images for use in the evaluation of contrast agent-based ultrasound exams. In the sequence of images multiple Regions Of Interest (ROI) can be selected. Inside these chosen regions the average gray value or the number of color pixels is calculated over time. Quanticon is intended an add-on accessory to existing diagnostic ultrasound systems. Quanticon is intended as a general digital ultrasound processing and archiving tool for use in cardiology, radiology, and neurology.

The EchoTech EasyStress system is indicated for the acquisition of heart cycle (R-Peak) triggered sequences of 2D ultrasound images for use in performing, scoring, measuring, reporting, and archiving stress echo studies. The EasyStress system utilizes the ASE Standard for Wall Motion Scoring to quantify wall motion abnormalities of the heart. EasyStress is an add-on accessory to existing diagnostic ultrasound systems. EasyStress is a digital ultrasound image processing and archiving tool for use in cardiology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K013088

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐